

# Exhibit R

## Emergency Use Authorization



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## About Emergency Use Authorizations (EUAs)

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of MCMs needed during public health emergencies.

What is an EUA?



Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act ([/federal-food-drug-and-cosmetic-act-fdc-act](#))), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Section 564 of the FD&C Act was amended by the Project Bioshield Act of 2004 ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#bioshield](#)) and was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pandemic-and-all-hazards-preparedness-reauthorization-act-2013-pahpra](#)) (PAHPRA), the 21st Century Cures Act ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#21CC](#)) of 2016, and Public Law 115-92 ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#PL11592](#)) of 2017.

Please note: a determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020 (<https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>), does not enable FDA to issue EUAs. A separate determination and declaration are needed under section 564 of the Federal Food, Drug and Cosmetic Act to enable FDA to issue EUAs, provided other statutory criteria are met.

Information on terminated and revoked EUAs can be found in archived information ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information](#)).

## Public Readiness and Emergency Preparedness Act (PREP Act)

Information on the PREP Act can be found here (<https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>).

The PREP Act amended the Public Health Service Act (PHS Act) to add section 319F-3 (42 U.S.C. 247d-6d). The HHS Secretary has issued several Declarations pursuant to section 319F-3 of the PHS Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

### PREP Act - COVID-19 Related Information

- Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19 (<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>) (February 4, 2020)
- Amended April 10, 2020 to add countermeasures pursuant to the CARES Act (<https://www.federalregister.gov/documents/2020/04/15/2020-08040/amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical>)
- COVID-19 - Medical Countermeasures (effective February 4, 2020) Amended April 10, 2020 to add countermeasures pursuant to the CARES Act OGC Advisory Opinion on PREP Act Declaration (<https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf>)
- Advisory Opinion 02-02 on the PREP Act and the Secretary's Declaration under the Act (<https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>)
- Second Amendment to Declaration under the PREP Act for Medical Countermeasures against COVID-19 (<https://www.federalregister.gov/documents/2020/06/08/2020-12465/second-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for>)
- Third Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (<https://www.federalregister.gov/documents/2020/08/24/2020-18542/third-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical>)

- Fourth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration (<https://www.federalregister.gov/documents/2020/12/09/2020-26977/fourth-amendment-to-the-declaration-under-the-public-readiness-and-emergency-preparedness-act-for>)
- Fifth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (<https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID-Amendment5.aspx>)

## Guidance

In January 2017, FDA finalized the guidance: Emergency Use Authorization of Medical Products and Related Authorities (</regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>). For more information, please see the January 13, 2017 Federal Register notice (<https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and>).

[Printable PDF \(288 KB\) \(/media/97321/download\)](/media/97321/download)

In addition, in January 2014, FDA issued a question and answer document (</media/87718/download>) (PDF, 762K) to respond to questions raised by public health stakeholders about PAHPRA's amendments to the EUA authority and establishment of new authorities related to the emergency use of MCMs during CBRN emergencies.

## Coronavirus Disease 2019 (COVID-19) EUA Information

- **Coronavirus Disease (COVID-19) updates from FDA** (</emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>)
- **Overviews:**
  - **FDA Combating COVID-19 With Medical Devices** (</media/136702/download>) (PDF, 708 KB)
  - **FDA Combating COVID-19 With Therapeutics** (</media/136832/download>) (PDF, 610 KB)
  - **EUA Authorized Serology Test Performance** (</medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance>)
- **Detailed Information for all COVID-19 EUAs, including authorizations and fact sheets**
  - In Vitro Diagnostic Products
  - Personal Protective Equipment and Related Devices
  - Ventilators and Other Medical Devices
  - Drug and Biological Products

### *In Vitro* Diagnostic Products

On February 4, 2020, the HHS Secretary determined that there is a public health emergency (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>) that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19. The EUAs subsequently issued by FDA are listed in the table below this blue box.

In continuing response to the COVID-19 pandemic, on March 24, 2020 (<https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration>), and based on the February 4, 2020 HHS EUA determination, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak. EUAs for home collection kits reference this declaration.

On February 29, 2020, the FDA issued an immediately in effect guidance (</regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>) with policy specific to development of in vitro diagnostic tests during this public health emergency. This guidance was updated on March 16, 2020, May 4, 2020, and May 11, 2020.

CDC has granted a right of reference to the performance data contained in CDC's EUA (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for these EUA submissions (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) are available to help facilitate the preparation, submission, and authorization of an EUA.

If you need additional information, please refer to the FAQs on Diagnostic Testing for SARS-CoV-2 (/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) and CLIA and University Laboratory Testing FAQ (<https://www.cms.gov/files/document/clia-university-lab-testing.pdf>) (CMS)

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| Date EUA First Issued | Most Recent Authorization or Revision | Entity                              | Diagnostic (Most Recent Letter of Authorization) (PDF)   | Product Attributes <sup>3, 4</sup>                        | Authorized Setting(s) <sup>1</sup> | Authorization Labeling <sup>2</sup> (PDF)  |
|-----------------------|---------------------------------------|-------------------------------------|--|---|------------------------------------|--|
| + 01/22/2021          | 01/22/2021                            | Ambry Genetics Laboratory           | Ambry COVID-19 RT-PCR Test ( <a href="http://wcms-internet.fda.gov/media/145406/download">http://wcms-internet.fda.gov/media/145406/download</a> ) (255KB) | Real-time RT-PCR, Home Collection, Saliva                 | H                                  | HCP ( <a href="http://wcms-internet.fda.gov/media/145407/download">http://wcms-internet.fda.gov/media/145407/download</a> ) (143KB)<br>Patients ( <a href="http://wcms-internet.fda.gov/media/145408/download">http://wcms-internet.fda.gov/media/145408/download</a> ) (129KB)<br>IFU (Home Collect) ( <a href="http://wcms-internet.fda.gov/media/145409/download">http://wcms-internet.fda.gov/media/145409/download</a> ) (1MB)<br>EUA Summary ( <a href="http://wcms-internet.fda.gov/media/145410/download">http://wcms-internet.fda.gov/media/145410/download</a> ) (442KB) |
| + 01/15/2021          | 01/15/2021                            | United Biomedical, Inc.             | UBI SARS-CoV-2 ELISA ( <a href="/media/145280/download">/media/145280/download</a> ) (119KB)   | Serology IgG, ELISA                                       | H                                  | HCP ( <a href="/media/145275/download">/media/145275/download</a> ) (144KB)<br>Recipients ( <a href="/media/145281/download">/media/145281/download</a> ) (129KB)<br>IFU ( <a href="/media/145277/download">/media/145277/download</a> ) (254KB)   |
| + 01/15/2021          | 01/15/2021                            | Bio-Rad Laboratories, Inc.          | Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit ( <a href="/media/145267/download">/media/145267/download</a> ) (128KB)                                       | Molecular Real-time RT-PCR                                | H                                  | HCP ( <a href="/media/145263/download">/media/145263/download</a> ) (146KB)<br>Patients ( <a href="/media/145268/download">/media/145268/download</a> ) (134KB)<br>IFU ( <a href="/media/145265/download">/media/145265/download</a> ) (6.36MB)  |
| + 01/13/2021          | 01/14/2021                            | SML GENETREE Co., Ltd.              | Ezplex SARS-CoV-2 G Kit ( <a href="/media/145131/download">/media/145131/download</a> ) (143KB)  | Molecular Real-time RT-PCR, Pooling                       | H                                  | HCP ( <a href="/media/145132/download">/media/145132/download</a> ) (155KB)<br>Patients ( <a href="/media/145133/download">/media/145133/download</a> ) (141KB)<br>IFU ( <a href="/media/145134/download">/media/145134/download</a> ) (1.99MB)  |
| + 01/11/2021          | 01/11/2021                            | Ortho Clinical Diagnostics, Inc.    | VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack ( <a href="/media/145069/download">/media/145069/download</a> ) (335KB)                   | Antigen Chemiluminescence Immunoassay, Instrument Read    | H, M                               | HCP ( <a href="/media/145070/download">/media/145070/download</a> ) (156KB)<br>Patients ( <a href="/media/145071/download">/media/145071/download</a> ) (194KB)<br>IFU ( <a href="/media/145073/download">/media/145073/download</a> ) (382KB)   |
| + 01/11/2021          | 01/19/2021                            | Phadia AB                           | EliA SARS-CoV-2-Sp1 IgG Test ( <a href="/media/145082/download">/media/145082/download</a> ) (156KB)   | Serology IgG, Fluoroenzyme Immunoassay, Semi-quantitative | H, M                               | HCP ( <a href="/media/145085/download">/media/145085/download</a> ) (147KB)<br>Recipients ( <a href="/media/145087/download">/media/145087/download</a> ) (129KB)<br>IFU ( <a href="/media/145089/download">/media/145089/download</a> ) (760KB)   |
| + 01/11/2021          | 01/11/2021                            | ADVAITE, Inc.                       | RapCov Rapid COVID-19 Test ( <a href="/media/145075/download">/media/145075/download</a> ) (359KB)   | Serology IgG, Lateral Flow, Fingerstick Whole Blood       | H, M, W                            | HCP ( <a href="/media/145077/download">/media/145077/download</a> ) (190KB)<br>Recipients ( <a href="/media/145078/download">/media/145078/download</a> ) (157KB)<br>IFU ( <a href="/media/145080/download">/media/145080/download</a> ) (923KB)   |
| + 01/08/2021          | 01/08/2021                            | Siemens Healthcare Diagnostics Inc. | Dimension EXL SARS-CoV-2 IgG (CV2G) ( <a href="/media/145012/download">/media/145012/download</a> ) (197KB)  | Serology IgG, CLIA, Semi-quantitative                     | H, M                               | HCP ( <a href="/media/145013/download">/media/145013/download</a> ) (167KB)<br>Recipients ( <a href="/media/145014/download">/media/145014/download</a> ) (149KB)<br>IFU ( <a href="/media/145015/download">/media/145015/download</a> ) (2.29MB)  |
| + 01/08/2021          | 01/08/2021                            | Siemens Healthcare Diagnostics Inc. | Dimension Vista SARS-CoV-2 IgG (COV2G) ( <a href="/media/145017/download">/media/145017/download</a> ) (192KB)   | Serology IgG, CLIA, Semi-quantitative                     | H, M                               | HCP ( <a href="/media/145018/download">/media/145018/download</a> ) (168KB)<br>Recipients ( <a href="/media/145019/download">/media/145019/download</a> ) (150KB)<br>IFU ( <a href="/media/145020/download">/media/145020/download</a> ) (2.29MB)  |
| + 01/05/2021          | 01/05/2021                            | Quanterix Corporation               | Simoa SARS-CoV-2 N Protein Antigen Test ( <a href="/media/144925/download">/media/144925/download</a> ) (153KB)  | Antigen Paramagnetic Microbead-based Immunoassay          | H, M                               | HCP ( <a href="/media/144926/download">/media/144926/download</a> ) (157KB)<br>Patients ( <a href="/media/144928/download">/media/144928/download</a> ) (146KB)<br>IFU ( <a href="/media/144929/download">/media/144929/download</a> ) (9.12MB)  |

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<sup>1</sup> Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

<sup>2</sup> Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.<sup>3</sup> Abbreviations: CLIA = chemiluminescence immunoassay; ELISA = enzyme-linked immunosorbent assay; ECLIA = electrochemiluminescence immunoassay; FMIA = fluorescent microsphere Immunoassay; CMIA = chemiluminescent microparticle immunoassay; RT-PCR = reverse transcriptase polymerase chain reaction; RT = reverse transcriptase; LAMP = loop-mediated isothermal amplification; MALDI-TOF = Matrix Assisted Laser Desorption/Ionization – Time of Flight; TMA = Transcription Mediated Amplification; qSTAR = Selective Temperature Amplification Reaction; CRISPR = clustered regularly interspaced short palindromic repeats<sup>4</sup> U = On March 31, 2020, FDA issued an umbrella EUA for High Complexity Molecular-Based Laboratory Developed Tests. The EUA letter of authorization is here (/media/136598/download). Tests that are authorized under this EUA are designated by "U" in the table.

## Personal Protective Equipment and Related Devices

For information on the applicable HHS Secretary determination and declaration supporting a particular EUA in the table below, as well as a link to any applicable PREP Act declaration, please use the expansion buttons on the left hand side of the table.

For additional information, please see Recent Final Medical Device Guidance Documents (/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents) and Coronavirus (COVID-19) Update: FDA takes action to increase U.S. supplies through instructions for PPE and device manufacturers (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-increase-us-supplies-through-instructions-ppe-and).

Please also see the Non-NIOSH Approved Respirator FAQ (/medical-devices/emergency-situations-medical-devices/non-niosh-approved-respirator-eua-faq) for additional information.

On August 20, 2020, the umbrella EUA for certain protective barrier enclosures was revoked (/media/141415/download). (See also the FDA's letter to healthcare providers (/medical-devices/letters-health-care-providers/protective-barrier-enclosures-without-negative-pressure-used-during-covid-19-pandemic-may-increase) and statement (/news-events/fda-brief/fda-brief-fda-revokes-emergency-use-authorization-protective-barrier-enclosures-without-negative).)

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| Date of First EUA Issuance | Most Recent Letter of Authorization (PDF)   | Appendix (PDF) | Authorized Labeling (PDF)  |
|----------------------------|---|----------------|--|
| + 01/15/2021               | Yale New Haven Health FFR Decontamination System (/media/145284/download) (145KB) |                | <ul style="list-style-type: none"> <li>• Fact Sheet for Healthcare Personnel (/media/145285/download) (117KB)</li> <li>• Instructions for Healthcare Personnel, Healthcare Facilities, and Community Partners (/media/145287/download) (113KB)</li> <li>• Instructions for Decontamination Personnel at Yale New Haven Health System (/media/145286/download) (138KB)</li> </ul> |

| Date of First EUA Issuance | Most Recent Letter of Authorization (PDF)  | Appendix (PDF) | Authorized Labeling (PDF)   |
|----------------------------|--|----------------|---|
| + 12/18/2020               | SCONE (/media/144674/download) (428KB)   |                | <ul style="list-style-type: none"> <li>Fact Sheet for Patients (/media/144675/download) (127KB)</li> <li>Fact Sheet for Healthcare Providers (/media/144676/download) (147KB)</li> <li>Instructions for Healthcare Providers and Facilities (/media/144677/download) (1.36MB)</li> </ul>  |
| + 12/04/2020               | Ecolab's Bioquell Technology System (/media/144223/download) (128KB)                     |                | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Personnel (/media/144213/download) (94KB)</li> <li>Instructions for Healthcare Personnel (/media/144215/download) (114KB)</li> <li>Instructions for Healthcare Facilities (/media/144216/download) (259KB)</li> <li>Setup Verification Form (/media/144217/download) (115KB)</li> <li>BQ-50 User Manual (/about-fda/page-not-found) (3.84MB)</li> <li>ProTeQ User Manual (/about-fda/page-not-found) (5.29MB)</li> </ul> |
| + 12/03/2020               | Lumin LM3000 Bioburden Reduction UV System (/media/144147/download) (100KB)              |                | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Providers (/media/144148/download) (169KB)</li> <li>Instructions for Healthcare Facilities (/media/144149/download) (549KB)</li> <li>Instructions for Healthcare Personnel (/media/144150/download) (171KB)</li> </ul>   |
| + 10/20/2020               | Roxby Development Zoe-Ann Decontamination System (/media/143149/download) (88KB)         |                | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Personnel (/media/143150/download) (165KB)</li> <li>Instructions for Healthcare Personnel (/media/143151/download) (344KB)</li> <li>Instructions for Healthcare Facilities (/media/143152/download) (381KB)</li> </ul>   |
| + 09/24/2020               | COVIAGE (/media/142447/download) (104KB)   |                | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Providers (/media/142450/download) (153KB)</li> <li>Fact Sheet for Patients (/media/142451/download) (131KB)</li> <li>Instructions for Healthcare Facilities: Assembly, Disassembly, and Disinfection of COVIAGE (/media/142448/download) (3.1MB)</li> <li>Instructions for Healthcare Personnel (HCP): Use of COVIAGE (/media/142449/download) (518KB)</li> </ul>   |
| + 08/20/2020               | Nova2200 for Decontaminating Compatible N95 Respirators (/media/141382/download) (258KB) |                | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Personnel (/media/141383/download) (143KB)</li> <li>Instructions for Healthcare Facilities (/media/141384/download) (176KB)</li> <li>Instructions for Healthcare Personnel (/media/141385/download) (149KB)</li> <li>Instructions for Decontamination Personnel (/media/141386/download) (1.13MB)</li> </ul>   |

| Date of First EUA Issuance | Most Recent Letter of Authorization (PDF)   | Appendix (PDF)   | Authorized Labeling (PDF)  |
|----------------------------|---|--|--|
| + 08/05/2020               | Surgical Masks<br>(/media/140894/download) (101KB)  | Appendix A: Authorized Surgical Masks (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixasurgicalmasks) (updated October 28, 2020) | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Personnel (/media/140895/download) (140KB)</li> </ul>   |
| + 07/24/2020               | Airway Dome<br>(/media/140455/download) (103KB)   |  | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Providers (/media/140452/download) (146KB)</li> <li>Fact Sheet for Patients (/media/140456/download) (124KB)</li> <li>Instructions for Healthcare Facilities: Assembly and Disposal of the Airway Dome (/media/140453/download) (2.05MB)</li> <li>Instructions for Healthcare Provider (HCP): Use of the Airway Dome (/media/140454/download) (2.04MB)</li> </ul> |
| + 07/24/2020               | Michigan State University Decontamination System<br>(/media/140472/download) (149KB)<br>(Reissued January 21, 2021) |  | <ul style="list-style-type: none"> <li>Fact Sheet for Healthcare Personnel (/media/140468/download) (148KB)</li> <li>Instructions for Michigan State University Staff (/media/140471/download) (236KB)</li> <li>Instructions for Healthcare Facilities and Operator Teams (/media/140469/download) (359KB)</li> <li>Instructions for Healthcare Personnel (/media/140470/download) (161KB)</li> </ul>                              |

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## Ventilators and Other Medical Devices

In continuing response to the COVID-19 pandemic, on March 24, 2020, and based on the February 4, 2020 HHS EUA determination, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak. The EUAs FDA subsequently authorized based on this determination and declaration are listed in the table below this blue box.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (<https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration>) (March 24, 2020)

The HHS Secretary issued a Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

- Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19 (<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>) (February 4, 2020)

Templates for these EUA submissions (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ventilators) are available to help facilitate the preparation, submission, and authorization of an EUA.

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Date EUA First Issued

Device Type

Most Recent Letter of Authorization (PDF)

Appendix to Letter and Other Documents (PDF)

Fact Sheets (PDF)



| Date EUA First Issued | Device Type                         | Most Recent Letter of Authorization (PDF)  | Appendix to Letter and Other Documents (PDF)  | Fact Sheets (PDF)  |
|-----------------------|-------------------------------------|--|---|--|
| + 11/21/2020          | Extracorporeal Membrane Oxygenation | Terumo Cardiovascular CAPIOX Emergency Bypass System (/media/144040/download) (363KB)  | <ul style="list-style-type: none"> <li>IFU (/media/144044/download) (9.44MB)</li> </ul>   | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/144041/download) (144KB)</li> <li>Patients (/media/144043/download) (143KB)</li> </ul> |
| + 09/24/2020          | Predictive Screening                | COViage Hemodynamic Instability and Respiratory Decompensation Prediction System (COViage), Dascena, Inc. (/media/142454/download) (112KB) | <ul style="list-style-type: none"> <li>IFU (/media/142453/download) (93KB)</li> </ul>   | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/142452/download) (199KB)</li> <li>Patients (/media/142455/download) (141KB)</li> </ul> |
| + 08/10/2020          | CRRT Set                            | Baxter Healthcare Corporation, Prismaflex HF20 Set (/media/141031/download) (96KB)   | <ul style="list-style-type: none"> <li>Prismaflex HF20 Set - IFU (/media/141034/download) (3.16MB)</li> <li>Prismaflex HF20 Set - IFU Insert (/media/141035/download) (28KB)</li> </ul>   | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/141032/download) (148KB)</li> <li>Patients (/media/141033/download) (166KB)</li> </ul> |
| + 08/03/2020          | Left Ventricular Support System     | Abiomed, Inc., Impella LV Systems (/media/140762/download) (165KB)   | <ul style="list-style-type: none"> <li>IFU - Impella Ventricular Support System 2.5, CP, 5.0, and LD (/media/140765/download) (17.9MB)</li> <li>IFU - Impella Ventricular Support System 5.5 (/media/140766/download) (8.99MB)</li> <li>IFU - Impella Ventricular Support System CP (/media/140767/download) (11.40MB)</li> </ul> | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/140763/download) (190KB)</li> <li>Patients (/media/140764/download) (159KB)</li> </ul> |
| + 07/10/2020          | Non-Invasive Vagus Nerve Stimulator | electroCore, Inc., gammaCore Sapphire CV (/media/139967/download) (367KB)  | <ul style="list-style-type: none"> <li>IFU (/media/139970/download) (814KB)</li> </ul>  | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/139968/download) (153KB)</li> <li>Patients (/media/139969/download) (139KB)</li> </ul> |
| + 05/29/2020          | Right Ventricular Assist Catheter   | Abiomed, Inc., Impella RP System (/media/138460/download) (142KB)  | <ul style="list-style-type: none"> <li>Impella RP System Instructions for Use (/media/138463/download) (4.39MB)</li> </ul>  | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/138461/download) (214KB)</li> <li>Patients (/media/138462/download) (183KB)</li> </ul> |
| + 05/26/2020          | Predictive Screening                | CLEW Medical Ltd., CLEWICU System (/media/138369/download) (105KB)   | <ul style="list-style-type: none"> <li>CLEWICU - IFU (/media/138372/download) (1.22MB)</li> <li>Letter Granting EUA Amendment(s) (June 30, 2020) (/media/139801/download) (108KB)</li> </ul>  | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/138370/download) (148KB)</li> <li>Patients (/media/138371/download) (132KB)</li> </ul> |
| + 05/20/2020          | CRRT Set                            | Baxter Healthcare Corporation, Prismaflex ST Set (/media/138254/download) (355KB)  | <ul style="list-style-type: none"> <li>Prismaflex ST Set - IFU - Global (/media/138252/download) (6.12MB)</li> <li>Prismaflex ST Set - IFU - South Korea (/media/138257/download) (4.82MB)</li> <li>Prismaflex ST Set - IFU - China (/media/138255/download) (5.08MB)</li> </ul>  | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/138256/download) (300KB)</li> <li>Patients (/media/138253/download) (205KB)</li> </ul> |

| Date EUA First Issued | Device Type                        | Most Recent Letter of Authorization (PDF)                                | Appendix to Letter and Other Documents (PDF)  | Fact Sheets (PDF)  |
|-----------------------|------------------------------------|--|---|--|
| + 05/14/2020          | Remote Patient QT Interval Monitor | G Medical Innovations, Ltd., VSMS Patch (/media/138105/download) (107KB) | <ul style="list-style-type: none"> <li>Professional User Guide, VSMS Patch (/media/138108/download) (2.07MB)</li> <li>Quick Start Guide, VSMS Patch (/media/138109/download) (943KB)</li> </ul> | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/138104/download) (112KB)</li> <li>Patients (/media/138107/download) (110KB)</li> </ul> |
| + 05/11/2020          | LVEF Screen                        | Eko Devices, Inc, ELEFT (/media/137932/download) (379KB)                 | <ul style="list-style-type: none"> <li>IFU (/media/137931/download) (249KB)</li> </ul>  | <ul style="list-style-type: none"> <li>Healthcare Providers (/media/137930/download) (248KB)</li> <li>Patients (/media/137929/download) (179KB)</li> </ul> |

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<sup>1</sup> The multiBic/multiPlus Solutions include multiBic dialysate and replacement fluid and multiPlus dialysate. The multiFiltrate PRO System, multiBic dialysate and the multiPlus dialysate solutions are regulated as devices by CDRH. The multiBic replacement fluid is regulated as a drug by CDER.

## Drug and Biological Products

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, effective March 27, 2020. The EUAs subsequently issued by FDA are listed in the table below this blue box.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>) (February 4, 2020)
- Emergency Use Authorization Declaration (<https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration>) (March 27, 2020)

On June 15, 2020, based on FDA's continued review of the scientific evidence available for hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) to treat COVID-19, FDA has determined that the statutory criteria for EUA as outlined in Section 564(c)(2) of the Food, Drug, and Cosmetic Act are no longer met. Specifically, FDA has determined that CQ and HCQ are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events (</drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>) and other serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use. This warrants revocation of the EUA (</media/138945/download>) for HCQ and CQ for the treatment of COVID-19.

- Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate (PDF, 125 KB) (</media/138946/download>)
  - Español (</media/139648/download>) (PDF-159KB); 简体中文 (</media/139647/download>) (PDF-264KB); 한국어 (</media/139646/download>) (PDF-440KB); Tagalog (</media/139649/download>) (PDF-118KB); Việt (</media/139650/download>) (PDF-245KB)

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| Date of First EUA Issuance | Most Recent Letter of Authorization (PDF) | Authorized Use <sup>1</sup> | Fact Sheets and Manufacturer Instructions/ Package Insert (PDF) |
|----------------------------|---|-----------------------------|---|
|----------------------------|---|-----------------------------|---|

| Date of First EUA Issuance | Most Recent Letter of Authorization (PDF)  | Authorized Use <sup>1</sup>  | Fact Sheets and Manufacturer Instructions/ Package Insert (PDF)   |
|----------------------------|--|--|---|
| + 12/18/2020               | Moderna COVID-19 Vaccine<br>(/media/144636/download) (437KB)   | For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older  | <p>Healthcare Providers (/media/144637/download) (418KB)</p> <ul style="list-style-type: none"> <li>View the Fact Sheet for Healthcare Providers Administering Vaccine in multiple additional languages (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#translated)</li> </ul> <p>Recipients and Caregivers<br/>(/media/144638/download) (314KB)</p> <ul style="list-style-type: none"> <li>View the Fact Sheet for Recipients and Caregivers in multiple additional languages (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#translated)</li> </ul> <p>Decision Memorandum (/media/144673/download) (769KB)</p> <p>Frequently Asked Questions on the Moderna COVID-19 Vaccine (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/moderna-covid-19-vaccine-frequently-asked-questions)</p> <p>More information about the Moderna COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine)</p> |
| + 12/11/2020               | <p>Pfizer-BioNTech COVID-19 Vaccine<br/>(/media/144412/download) (421KB) (Reissued December 23, 2020)</p> <p>Letter Granting EUA Amendment (January 6, 2021)<br/>(/media/144955/download) (164KB)</p> <p>Letter Granting EUA Amendment (January 22, 2021)<br/>(/media/145493/download) (190KB)</p> | For the prevention of 2019 coronavirus disease (COVID-19) for individuals 16 years of age and older  | <p>Healthcare Providers (/media/144413/download) (1.16MB)</p> <p>Recipients and Caregivers<br/>(/media/144414/download) (190KB)</p> <ul style="list-style-type: none"> <li>View the Fact Sheet for Recipients and Caregivers in multiple additional languages (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine#translated)</li> </ul> <p>Decision Memorandum (/media/144416/download) (709KB)</p> <p>Frequently Asked Questions on the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions)</p> <p>More information about the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine)</p>   |
| + 11/21/2020               | Casirivimab and Imdevimab<br>(/media/143891/download) (375KB)  | Casirivimab and imdevimab to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. | <p>Healthcare Providers (/media/143892/download) (431KB)</p> <ul style="list-style-type: none"> <li>Spanish (/media/145510/download) (516KB)</li> </ul> <p>Patients, Parents, and Caregivers<br/>(/media/143893/download) (110KB)</p> <p>Dear Healthcare Provider Letter (/media/143901/download) (1.09MB)</p> <p>Information Sheet ("Fact Sheet Directions")<br/>(/media/143902/download) (46KB)</p> <ul style="list-style-type: none"> <li>Spanish (/media/145508/download) (132KB)</li> </ul> <p>Frequently Asked Questions on the Emergency Use Authorization of Casirivimab + Imdevimab<br/>(/media/143894/download) (324KB)</p> <p>CDER Review Document (/media/144468/download) (3.60MB)</p>   |

| Date of First EUA Issuance | Most Recent Letter of Authorization (PDF)  | Authorized Use <sup>1</sup>   | Fact Sheets and Manufacturer Instructions/ Package Insert (PDF)   |
|----------------------------|--|---|---|
| + 11/19/2020               | Baricitinib (Olumiant) in Combination with remdesivir (Veklury) (/media/143822/download) (322KB)   | For emergency use by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).                  | Healthcare Providers (/media/143823/download) (155KB)<br>Patients, Parents, and Caregivers (/media/143824/download) (55KB)<br>Frequently Asked Questions on the Emergency Use Authorization for Olumiant (baricitinib) in Combination with Veklury (remdesivir) for Treatment of Mild to Moderate COVID-19 (/media/143825/download) (270KB)<br>CDER Review Document (/media/144473/download) (1.39MB) |
| + 11/09/2020               | Bamlanivimab (/media/143602/download) (374KB)  | For the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. | Healthcare Providers (/media/143603/download) (444KB)<br>Patients, Parents, and Caregivers (/media/143604/download) (132KB)<br>• Spanish (/media/143645/download) (132KB)<br>Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab (/media/143605/download) (250KB)<br>CDER Review Document (/media/144118/download) (2.28MB)  |
| + 08/23/2020               | COVID-19 convalescent plasma (/media/141477/download) (302KB) (Reissued November 30, 2020)   | For the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19)   | Healthcare Providers (/media/141478/download) (222KB)<br>Patients and Parents/ Caregivers (/media/141479/download) (142KB)<br>Summary Information 9/23/2020 (/media/142386/download) (380KB)<br>Decision Memorandum (/media/141480/download) (505KB)<br>Emergency Use Authorization request (/media/141481/download) (510KB)  |
| + 08/13/2020               | REGIOCIT replacement solution that contains citrate for regional citrate anticoagulation (RCA) of the extracorporeal circuit (/media/141168/download) (92KB) | To be used as a replacement solution only in adult patients treated with continuous renal replacement therapy (CRRT), and for whom regional citrate anticoagulation is appropriate, in a critical care setting  | Healthcare Providers (/media/141170/download) (108KB)<br>Patients and Caregivers (/media/141172/download) (52KB)<br>REGIOCIT package insert for EUA (/media/141186/download) (140KB)  |
| + 05/08/2020               | Fresenius Kabi Propoven 2% (/media/137888/download) (209KB)  | To maintain sedation via continuous infusion in patients older than age 16 with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting <sup>2</sup>   | Healthcare Providers (/media/137889/download) (288KB)<br>Patients and Parent/Caregivers (/media/137890/download) (39KB)<br>Propoven 2% Wall Chart (/media/137891/download) (2.4MB)  |

| Date of First EUA Issuance | Most Recent Letter of Authorization (PDF)  | Authorized Use <sup>1</sup>   | Fact Sheets and Manufacturer Instructions/ Package Insert (PDF)   |
|----------------------------|--|---|---|
| + 05/01/2020               | Remdesivir for Certain Hospitalized COVID-19 Patients (/media/137564/download) (423KB) (Reissued October 22, 2020)   | <p>For emergency use by licensed healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.</p> <p>On October 22, 2020, FDA approved Veklury (remdesivir) (/news-events/press-announcements/fda-approves-first-treatment-covid-19) for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. This approval does not include the entire population that had been authorized to use Veklury under an Emergency Use Authorization (EUA) originally issued on May 1, 2020. In order to ensure continued access to the pediatric population previously covered under the EUA, the EUA for Veklury continues to authorize Veklury for emergency use by licensed healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.</p> <p>For additional information, also see: FDA's approval of Veklury (remdesivir) for the treatment of COVID-19—The Science of Safety and Effectiveness (/drugs/drug-safety-and-availability/fdas-approval-veklury-remdesivir-treatment-covid-19-science-safety-and-effectiveness)</p> | <p>Healthcare Providers (/media/137566/download) (375KB)</p> <p>Patients and Parent/ Caregivers (/media/137565/download) (94KB)</p> <ul style="list-style-type: none"> <li>Spanish (/media/139460/download) (563KB)</li> </ul> <p>Frequently Asked Questions on the EUA for Veklury (remdesivir) for Certain Hospitalized Patients (/media/137574/download) (212KB) (Updated January 14, 2021)</p> <ul style="list-style-type: none"> <li>Spanish (/media/138804/download) (195KB)</li> </ul>                   |
| + 04/30/2020               | Fresenius Medical, multiFiltrate PRO System and multiBic/multiPlus Solutions (/media/137520/download) (171KB) <sup>3</sup> [also listed under Medical Device EUAs] | To provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the COVID-19 pandemic.   | <p>Healthcare Providers (/media/137522/download) (135KB)</p> <p>Patients (/media/137521/download) (125KB)</p> <p>Instructions for Use, Bloodline/ Tubing (/media/137523/download) (83KB)</p> <p>Instructions for Use, UltraFlux (/media/137527/download) (147KB)</p> <p>Instructions for Use, multiFiltratePRO (/media/137528/download) (15.07MB)</p> <p>Summary of Product Characteristics (SmPC) (/media/137524/download) (308KB)</p> <p>Instructions for Use, MultiPlus (/media/137526/download) (110KB)</p> |

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<sup>1</sup> The virus that causes COVID-19 has led to an increased number of patients requiring critical care, such as with severe respiratory illness. As a result, there is a shortage of adequate, FDA-approved drugs used for their treatment, such as propofol for sedation of mechanically ventilated patients.

<sup>2</sup> In the circumstances of this public health emergency, it would not be feasible to require healthcare providers to seek to limit Fresenius Propoven 2% Emulsion only to be used for patients with suspected or confirmed COVID-19; therefore, this authorization does not limit use to such patients.

<sup>3</sup> The multiBic/multiPlus Solutions include multiBic dialysate and replacement fluid and multiPlus dialysate. The multiBic replacement fluid is regulated as a drug by CDER. The multiFiltrate PRO System, multiBic dialysate and the multiPlus dialysate solutions are regulated as devices by CDRH.

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## Other Current EUAs

The tables below provide information on current EUAs:

- [Anthrax EUAs](#)
- [Ebola Virus EUA Information](#)
- [Enterovirus D68 \(EV-D68\) EUA Information](#)
- [Freeze Dried Plasma Information](#)
- [H7N9 Influenza EUA Information](#)
- [Middle East Respiratory Syndrome Coronavirus \(MERS-CoV\) EUA Information](#)
- [Nerve Agent EUA Information](#)
- [Zika Virus EUA Information](#)

Information about EUAs that are no longer in effect is available on our EUA archive page (</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information>).

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### Anthrax EUAs

The 2016 FDA Doxycycline Emergency Dispensing Order (</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders#doxy>) and CDC Doxycycline Emergency Use Instructions (EUI) (</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders#doxy>) together replace the need for the doxycycline mass dispensing EUA (issued on July 21, 2011). Therefore, the doxycycline emergency dispensing order and EUI should be used by stakeholders for anthrax preparedness and response instead of the mass dispensing EUA.

The July 21, 2011, doxycycline mass dispensing EUA, and the October 14, 2011, National Postal Model anthrax EUA will be terminated by FDA, and notice of such termination will be published in the *Federal Register*. For additional information, see Emergency Use Authorization–Archived Information (</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information>).

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### Ebola Virus EUA Information

**[Ebola preparedness and response updates from FDA \(/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda\)](/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda)** (all agency activities)

**For more information about the diagnostics below, also see [Emergency Use Authorizations \(/about-fda/page-not-found\)](/about-fda/page-not-found)** (current device EUAs).

### Ebola Diagnostic Tests with De Novo, 510(k) or PMA

- **OraQuickEbola Rapid Antigen Test** (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN190025>) - On October 10, 2019, FDA allowed marketing ([https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/DEN190025.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190025.pdf)) (PDF, 255 KB) of a rapid diagnostic test (RDT) to detect Ebola virus antigens (proteins) in human blood from certain living individuals and samples from certain recently deceased individuals suspected to

have died from Ebola (cadaveric oral fluid). The OraQuick Ebola Rapid Antigen Test is the first rapid diagnostic test the FDA has allowed to be marketed in the U.S. for Ebola virus disease (EVD). The test provides a rapid, presumptive diagnosis that must be confirmed. *Also see the FDA news release: FDA allows marketing of first rapid diagnostic test for detecting Ebola virus antigens (/news-events/press-announcements/fda-allows-marketing-first-rapid-diagnostic-test-detecting-ebola-virus-antigens)*

The OraQuick Ebola Test was reviewed under the De Novo premarket review pathway (/medical-devices/premarket-submissions/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this marketing authorization, the FDA is establishing criteria, called special controls, that determine the requirements for demonstrating accuracy, reliability and effectiveness of tests intended to identify Ebola virus antigens. These special controls, when met along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

| Medical Product                                   | Date of EUA Issuance   | Letter of Authorization  | Federal Register Notice for EUA   | Fact Sheets and Manufacturer Instructions/Package Insert   | El                       |
|---|--|--|---|--|--------------------------|
| EZ1 Real-time RT-PCR Assay (DoD)                  | August 5, 2014 (initial issuance)<br>October 10, 2014 (reissuance)                             | Authorization (/media/89984/download) (PDF, 61 KB)   | FR notice ( <a href="https://www.federalregister.gov/articles/2014/09/17/2014-22086/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus">https://www.federalregister.gov/articles/2014/09/17/2014-22086/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus</a> ) | <ul style="list-style-type: none"> <li>Healthcare (/media/89986/download) (PDF, 58 KB)</li> <li>Patients (/media/89988/download) (PDF, 59 KB)</li> <li>Instruction Booklet (/media/89989/download) (PDF, 1.1 MB)</li> </ul>    | D<br>D<br>(t<br>1'<br>di |
| CDC Ebola Virus NP Real-time RT-PCR Assay (CDC)   | October 10, 2014 (initial issuance)<br>March 2, 2015 (reissuance)<br>October 8, 2019 (amended) | Authorization (/media/91083/download) (PDF, 282 KB)<br>Letter granting EUA amendment(s) (PDF, 134 KB) (/media/131606/download) | FR notice ( <a href="https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus">https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus</a> )   | <ul style="list-style-type: none"> <li>Healthcare (/media/91087/download) (PDF, 207 KB)</li> <li>Patients (/media/91092/download) (PDF, 149 KB)</li> <li>Instructions for Use (/media/91097/download) (PDF, 496 KB)</li> </ul> | D<br>D<br>(t<br>1'<br>di |
| CDC Ebola Virus VP40 Real-time RT-PCR Assay (CDC) | October 10, 2014 (initial issuance)<br>March 2, 2015 (reissuance)<br>October 8, 2019 (amended) | Authorization (/media/91105/download) (PDF, 285 KB)<br>Letter granting EUA amendment(s) (PDF, 135 KB) (/media/131605/download) | FR notice ( <a href="https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus">https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus</a> )   | <ul style="list-style-type: none"> <li>Healthcare (/media/91111/download) (PDF, 207 KB)</li> <li>Patients (/media/91118/download) (PDF, 149 KB)</li> <li>Instructions for Use (/media/91142/download) (PDF, 494 KB)</li> </ul> | D<br>D<br>(t<br>1'<br>di |
| FilmArray NGDS BT-E Assay (Biofire Defense, LLC)  | October 25, 2014 (initial issuance)<br>March 2, 2015 (reissuance)                              | Authorization (/media/91070/download) (PDF, 326 KB)  | FR notice ( <a href="https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus">https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus</a> )               | <ul style="list-style-type: none"> <li>Healthcare (/media/91149/download) (PDF, 40 KB)</li> <li>Patients (/media/91153/download) (PDF, 40 KB)</li> <li>Instructions for Use (/media/91077/download) (PDF, 740 KB)</li> </ul>   | D<br>D<br>(t<br>1'<br>di |
| FilmArray Biothreat-E test (Biofire Defense, LLC) | October 25, 2014<br>November 12, 2019 (amended)  | Authorization (/media/89580/download) (PDF, 73 KB)<br>Letter granting EUA amendment(s) (PDF, 152 KB) (/media/132517/download)  | FR notice ( <a href="https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus">https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus</a> )               | <ul style="list-style-type: none"> <li>Healthcare (/media/89585/download) (PDF, 227 KB)</li> <li>Patients (/media/89604/download) (PDF, 191 KB)</li> <li>Instructions for Use (/media/89614/download) (PDF, 1.6 MB)</li> </ul> | D<br>D<br>(t<br>1'<br>di |

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| RealStar<br>Ebola virus RT-PCR Kit 1.0<br>(Altona Diagnostics, GmbH)    | November 10, 2014 (initial issuance)<br><br>November 26, 2014 (reissuance) | Authorization<br>(/media/123410/download)<br>(PDF, 263 KB)   | FR notice<br>( <a href="https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus">https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus</a> )               | <ul style="list-style-type: none"> <li>Healthcare<br/>(/media/120428/download) (PDF, 81 KB)</li> <li>Patients (/media/120429/download) (PDF, 92 KB)</li> <li>Instructions for Use<br/>(/media/120430/download) (PDF, 797 KB)</li> </ul>    | D<br>D<br>(t<br>1'<br>di |
| LightMix<br>Ebola Zaire rRT-PCR Test<br>(Roche Molecular Systems, Inc.) | December 23, 2014  | Authorization<br>(/media/120431/download)<br>(PDF, 2.2 MB)   | FR notice<br>( <a href="https://www.federalregister.gov/articles/2015/03/17/2015-06039/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus">https://www.federalregister.gov/articles/2015/03/17/2015-06039/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus</a> ) | <ul style="list-style-type: none"> <li>Healthcare<br/>(/media/120432/download) (PDF, 59 KB)</li> <li>Patients (/media/120433/download) (PDF, 60 KB)</li> <li>Instructions for Use (/about-fda/page-not-found) (PDF, 328 KB)</li> </ul>     | D<br>D<br>(t<br>1'<br>di |
| Xpert Ebola Assay<br>(Cepheid)  | March 23, 2015   | Authorization<br>(/media/91315/download)<br>(PDF, 240 KB)  | FR notice<br>( <a href="https://www.federalregister.gov/articles/2015/06/05/2015-13699/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus">https://www.federalregister.gov/articles/2015/06/05/2015-13699/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus</a> )               | <ul style="list-style-type: none"> <li>Healthcare<br/>(/media/91934/download) (PDF, 310 KB)</li> <li>Patients (/media/91939/download) (PDF, 211 KB)</li> <li>Instructions for Use<br/>(/media/91944/download) (PDF, 625 KB)</li> </ul>     | D<br>D<br>(t<br>1'<br>di |
| Idylla Ebola Virus Triage Test (Biocartis NV)                           | May 26, 2016   | Authorization<br>(/media/98460/download)<br>(PDF, 321 KB)  | FR notice<br>( <a href="https://www.federalregister.gov/articles/2016/07/08/2016-16176/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus">https://www.federalregister.gov/articles/2016/07/08/2016-16176/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus</a> )           | <ul style="list-style-type: none"> <li>Healthcare<br/>(/media/98451/download) (PDF, 203 KB)</li> <li>Patients<br/>(/media/98442/download) (PDF, 163 KB)</li> <li>Instructions for Use<br/>(/media/98434/download) (PDF, 2.1 MB)</li> </ul> | D<br>D<br>(t<br>1'<br>di |
| DPP Ebola Antigen System<br>(Chembio Diagnostic Systems, Inc.)          | November 9, 2018<br><br>April 2, 2019 (amended)                            | Authorization<br>(/media/117735/download)<br>(PDF, 103 KB)<br><br>Letter Granting EUA Amendment(s)<br>(/media/122553/download)<br>(PDF, 87 KB) | FR notice<br>( <a href="https://www.federalregister.gov/documents/2019/02/13/2019-02134/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-virus">https://www.federalregister.gov/documents/2019/02/13/2019-02134/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-virus</a> )           | <ul style="list-style-type: none"> <li>Healthcare<br/>(/media/117736/download) (PDF, 122 KB)</li> <li>Patients (/media/117737/download) (PDF, 119 KB)</li> <li>Instructions for Use<br/>(/media/117738/download) (PDF, 2 MB)</li> </ul>    | D<br>D<br>(t<br>1'<br>di |

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#### Enterovirus D68 (EV-D68) EUA Information

**For more information about the diagnostics below, also see Emergency Use Authorizations (/about-fda/page-not-found) (current device EUAs).**

| Medical Product | Date of EUA Issuance | Letter of Authorization | Federal Register Notice for EUA | Fact Sheets and Manufacturer Instructions/Package Insert | EUA Determination and Denial |
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| CDC<br>Enterovirus<br>D68 2014<br>Real-time<br>RT-PCR<br>Assay (EV-<br>D68 2014<br>rRT-PCR) | May 12,<br>2015 | Authorization<br>(/media/120425/download)<br>(PDF, 229 KB) | FR notice<br>(https://www.federalregister.gov/articles/2015/07/01/2015-<br>16125/authorization-of-emergency-use-of-an-in-vitro-<br>diagnostic-device-for-detection-of-enterovirus-d68) | <ul style="list-style-type: none"> <li>Healthcare<br/>(/media/92008/download)<br/>(PDF, 214 KB)</li> <li>Patients<br/>(/media/120426/download)<br/>(PDF, 150 KB)</li> <li>Instructions for Use<br/>(/media/120427/download)(PDF,<br/>531 KB)</li> </ul> | Determination and Declarat<br>New <i>In Vitro</i> Diagnostics fo<br>(https://www.federalregiste<br>04121/determination-and-c<br>use-of-new-in-vitro-diagnos<br>2015) |
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#### Freeze Dried Plasma Information

Also see FDA News Release: FDA takes action to support American military personnel by granting an authorization for freeze-dried plasma product to enable broader access while the agency works toward approval of the product (/news-events/press-announcements/fda-takes-action-support-american-military-personnel-granting-authorization-freeze-dried-plasma) (July 10, 2018)

| Medical Product  | Date of EUA Issuance  | Letter of Authorization   | Federal Register Notice for EUA   | Fact Sheets and Manufacturer Instructions/Package Insert  | EUA Determination and  |
|--|---|---|---|---|--|
| Pathogen-<br>Reduced<br>Leukocyte-<br>Depleted<br>Freeze<br>Dried<br>Plasma<br>(Centre de<br>Transfusion<br>Sanguine<br>des<br>Armées) | July 9, 2018<br>(initial<br>issuance)<br><br>May 8, 2020<br>(amendment) | Authorization<br>(/media/114282/download)<br>(PDF, 203 KB)<br><br>Letter granting EUA<br>amendments<br>(/media/137970/download)<br>(PDF, 60 KB) | FR notice<br>(https://www.federalregister.gov/documents/2018/08/13/2018-<br>17303/authorization-of-emergency-use-of-a-freeze-dried-<br>plasma-treatment-for-hemorrhage-or-coagulopathy) | <ul style="list-style-type: none"> <li>Fact Sheet for U.S. Military<br/>Medical Personnel<br/>(/media/119949/download)<br/>(PDF, 132 KB)</li> <li>Fact Sheet for Recipients<br/>(/media/119948/download)<br/>(PDF, 101 KB)</li> </ul> | Determination by DoD (.<br>Declaration Regarding E<br>Hemorrhage or Coagulc<br>Agents of Military Comt<br>(https://www.federalreg<br>16331/emergency-use-<br>hemorrhage-due-to-age<br>9, 2018) |

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#### H7N9 Influenza EUA Information

**For more information about the diagnostics below, also see Emergency Use Authorizations (/about-fda/page-not-found) (current device EUAs).**

| Medical Product | Date of EUA Issuance | Letter of Authorization | Federal Register Notice for EUA | Fact Sheet and Manufacturer Instructions/Package Insert | EUA Determination and Declarat |
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|---|--|---|---|--|---|
| CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay | April 22, 2013 (initial issuance)<br><br>March 27, 2018 (reissuance) | Authorization (/media/85910/download) (PDF, 301 KB), re-issued March 27, 2018   | FR notice ( <a href="https://www.federalregister.gov/articles/2013/06/25/2013-15096/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-the-novel-avian-influenza">https://www.federalregister.gov/articles/2013/06/25/2013-15096/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-the-novel-avian-influenza</a> ) | <ul style="list-style-type: none"> <li>Healthcare (/media/85915/download) (PDF, 46 KB)</li> <li>Patients (/media/85446/download) (PDF, 32 KB)</li> <li>Instructions for Use (/media/85454/download) (PDF, 433 KB)</li> </ul>   | Determination and Declaration R Diagnostics for Detection of the ( <a href="https://www.federalregister.gov/10055/determination-and-declar-vitro-diagnostics-for-detection-o">https://www.federalregister.gov/10055/determination-and-declar-vitro-diagnostics-for-detection-o</a> )<br><br>Additional information from HH§ ( <a href="http://www.phe.gov/emergency-influenza-virus.aspx">http://www.phe.gov/emergency-influenza-virus.aspx</a> ) |
| Quidel Lyra Influenza A Subtype H7N9 Assay  | February 14, 2014  | Authorization (/media/87767/download) (PDF, 57 KB)  | FR notice ( <a href="https://www.federalregister.gov/articles/2014/04/17/2014-08706/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a">https://www.federalregister.gov/articles/2014/04/17/2014-08706/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a</a> )   | <ul style="list-style-type: none"> <li>Healthcare (/media/87775/download) (PDF, 42 KB)</li> <li>Patients (/media/87780/download) (PDF, 40 KB)</li> </ul>   | Determination and Declaration R Diagnostics for Detection of the ( <a href="https://www.federalregister.gov/10055/determination-and-declar-vitro-diagnostics-for-detection-o">https://www.federalregister.gov/10055/determination-and-declar-vitro-diagnostics-for-detection-o</a> )<br><br>Additional information from HH§ ( <a href="http://www.phe.gov/emergency-influenza-virus.aspx">http://www.phe.gov/emergency-influenza-virus.aspx</a> ) |
| A/H7N9 Influenza Rapid Test   | April 25, 2014   | Authorization (/medical-devices/emergency-situations-medical-devices/ah7n9-influenza-rapid-test-letter-authorization) | FR notice ( <a href="https://www.federalregister.gov/articles/2014/06/23/2014-14547/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a">https://www.federalregister.gov/articles/2014/06/23/2014-14547/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a</a> )   | <ul style="list-style-type: none"> <li>Healthcare (/medical-devices/emergency-situations-medical-devices/fact-sheet-health-care-providers-interpreting-ah7n9-influenza-rapid-test-results)</li> <li>Patients (/medical-devices/emergency-situations-medical-devices/fact-sheet-patients-understanding-results-ah7n9-influenza-rapid-test)</li> </ul> | Determination and Declaration R Diagnostics for Detection of the ( <a href="https://www.federalregister.gov/10055/determination-and-declar-vitro-diagnostics-for-detection-o">https://www.federalregister.gov/10055/determination-and-declar-vitro-diagnostics-for-detection-o</a> )<br><br>Additional information from HH§ ( <a href="http://www.phe.gov/emergency-influenza-virus.aspx">http://www.phe.gov/emergency-influenza-virus.aspx</a> ) |

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#### Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EUA Information

**For more information about the diagnostics below, also see Emergency Use Authorizations** (/about-fda/page-not-found) **(current device EUAs).**

| Medical Product | Date of EUA Issuance | Letter of Authorization | Federal Register Notice for EUA | Fact Sheets and Manufacturer Instructions/Package Insert | EUA Determination : |
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| CDC Novel Coronavirus 2012 Real-time RT-PCR Assay | June 5, 2013 (initial issuance)<br><br>June 10, 2014 (reissuance)      | Authorization (/media/88518/download) (PDF, 2.2 MB) | FR notice ( <a href="https://www.federalregister.gov/documents/2013/07/17/2013-17103/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-middle-east-respiratory">https://www.federalregister.gov/documents/2013/07/17/2013-17103/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-middle-east-respiratory</a> ) | <ul style="list-style-type: none"> <li>Healthcare (/medical-devices/emergency-situations-medical-devices/fact-sheet-health-care-professionals-interpreting-cdc-novel-coronavirus-2012-real-time-rt-pcr-assay)</li> <li>Patients (/medical-devices/emergency-situations-medical-devices/fact-sheet-patients-understanding-results-cdc-novel-coronavirus-2012-real-time-rt-pcr-assay)</li> <li>Contacts (/media/88505/download) (PDF, 1.2 MB)</li> <li>Instructions for Use (/media/85951/download) (PDF, 743 KB)</li> </ul> | Determination and C Diagnostics for Dete Coronavirus (MERS- ( <a href="https://www.federa13333/determinatio-vitro-diagnostics-for">https://www.federa13333/determinatio-vitro-diagnostics-for</a> Additional informati ( <a href="http://www.phe.gov/cov.aspx">http://www.phe.gov/cov.aspx</a> ) |
| RealStar MERS-CoV RT-PCR Kit U.S.                 | July 17, 2015 (initial issuance)<br><br>February 12, 2016 (reissuance) | Authorization (/media/93040/download) (PDF, 238 KB) | FR notice ( <a href="https://www.federalregister.gov/documents/2015/09/01/2015-21585/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-middle-east">https://www.federalregister.gov/documents/2015/09/01/2015-21585/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-middle-east</a> )           | <ul style="list-style-type: none"> <li>Healthcare (/media/93048/download) (PDF, 269 KB)</li> <li>Patients (/media/93056/download) (PDF, 241 KB)</li> <li>Instructions for Use (/media/120434/download) (PDF, 1.28 MB)</li> <li>Fact Sheet for Asymptomatic Individuals Suspected of Exposure to MERS-CoV Cases (/media/95614/download) (PDF, 285 KB)</li> </ul>  | Determination and C Diagnostics for Dete Coronavirus (MERS- ( <a href="https://www.federa13333/determinatio-vitro-diagnostics-for">https://www.federa13333/determinatio-vitro-diagnostics-for</a> Additional informati ( <a href="http://www.phe.gov/cov.aspx">http://www.phe.gov/cov.aspx</a> ) |

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#### Nerve Agent EUA Information

On July 9, 2018, FDA approved ([https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2018/212319Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/212319Orig1s000ltr.pdf)) (PDF, 49 KB) the 2 mg Atropine Auto-Injector manufactured by Rafa Laboratories, Ltd., for the treatment of poisoning by susceptible organophosphorous nerve agents having cholinesterase activity as well as organophosphorous or carbamate insecticides in adults and pediatric patients weighing over 90 lbs [41 kg] (generally over 10 years of age). For more information about the approved 2 mg Rafa Atropine Auto-Injector, see the product label ([https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/212319s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/212319s000lbl.pdf)) (PDF, 482 KB). The EUA detailed in the table below is still in effect.

| Medical Product | Date of EUA Issuance | Letter of Authorization | Federal Register Notice for EUA | Fact Sheets and Manufacturer Instructions/Package Insert | EUA Determination and D |
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|---|---|--|--|---|---|
| Atropine<br>Auto-<br>Injector<br>(Rafa<br>Laboratories<br>Ltd.) | April 11,<br>2017<br>(initial<br>issuance)<br><br>May 23,<br>2017<br>(amended)<br><br>January<br>24, 2018<br>(amended)<br><br>March 6,<br>2018<br>(amended)<br><br>May 15,<br>2018<br>(amended) | Letter of Authorization<br>(/media/104550/download)<br>(PDF, 514 KB)<br><br>Letter granting EUA<br>amendment(s)<br>(/media/105590/download)<br>(PDF, 28 KB)<br><br>2nd letter granting EUA<br>amendment(s)<br>(/media/110881/download)<br>(PDF, 33 KB)<br><br>3rd letter granting EUA<br>amendment(s)<br>(/media/111656/download)<br>(PDF, 85 KB)<br><br>4th letter granting EUA<br>amendment(s)<br>(/media/113102/download)<br>(PDF, 42 KB) | FR<br>notice<br>(https://www.federalregister.gov/documents/2017/06/30/2017-13664/emergency-use-authorizations-injectable-treatment-for-nerve-agent-or-certain-insecticide) | <ul style="list-style-type: none"> <li>Healthcare<br/>(/media/104559/download)<br/>(PDF, 531 KB)</li> <li>Patients and Caregivers<br/>(/media/104564/download)<br/>(PDF, 675 KB)</li> </ul> | Determination and Declar<br>Certain Insecticide (Orgar<br>Poisoning<br>(https://www.federalregis<br>07685/determination-and<br>of-injectable-treatments-f |
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#### Zika Virus EUA Information

**Zika virus response updates from FDA** (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda)

**Zika virus diagnostic development information** (/emergency-preparedness-and-response/mcm-issues/zika-virus-diagnostic-development)

**For more information about the diagnostics below, also see Emergency Use Authorizations** (/about-fda/page-not-found) (current device EUAs).

Draft EUA review templates for Zika are available by email request to: CDRH-ZIKA-Templates@fda.hhs.gov (mailto:CDRH-ZIKA-Templates@fda.hhs.gov?Subject=EUA template request)

Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov (mailto:CDRH-EUA-Reporting@fda.hhs.gov), in addition to reporting concerns to the manufacturer.

#### Zika Diagnostic Tests with De Novo, 510(k), or PMA

- **ZIKV Detect 2.0 IgM Capture ELISA** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN180069) - On May 23, 2019, FDA authorized marketing (https://www.accessdata.fda.gov/cdrh\_docs/pdf18/DEN180069.pdf) (PDF, 175 KB) of the ZIKV Detect 2.0 IgM Capture ELISA to detect Zika virus immunoglobulin (IgM) antibodies in human blood. The ZIKV Detect 2.0 IgM Capture ELISA is the first Zika diagnostic test the FDA has allowed to be marketed in the U.S.; previously, tests for detecting Zika virus IgM antibodies—including the ZIKV Detect 2.0 IgM Capture ELISA—had been authorized only for emergency use under the FDA's EUA authority. *Also see the FDA news release: FDA authorizes marketing of first diagnostic test for detecting Zika virus antibodies* (/news-events/press-announcements/fda-authorizes-marketing-first-diagnostic-test-detecting-zika-virus-antibodies)
- **ADVIA Centaur Zika test** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K191578) – On July 17, 2019, FDA cleared the ADVIA Centaur Zika test. This is the second Zika diagnostic test FDA has allowed to be marketed in the U.S. for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.
- **LIAISON XL Zika Capture IgM Assay II** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K192046) – On October 28, 2019, FDA cleared the LIAISON XL Zika Capture IgM Assay II for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.
- **DPP Zika IgM Assay System** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K192046) – On June 3, 2020, FDA cleared a similar DPP Zika IgM System for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.

| Medical Product   | Date of EUA Issuance   | Letters  | Federal Register Notice for EUA  | Fact Sheets Instructions  |
|---|--|--|--|---|
| CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay<br><br><i>CDC statement on this EUA</i><br>( <a href="http://www.cdc.gov/media/releases/2016/s0226-laboratory-test-for-zika-virus.html">http://www.cdc.gov/media/releases/2016/s0226-laboratory-test-for-zika-virus.html</a> ) | February 26, 2016 (initial issuance)<br><br>June 29, 2016 (amended)<br><br>November 15, 2016 (amended)<br><br>December 6, 2016 (amended)<br><br>May 3, 2017 (amended)<br><br>July 31, 2017 (amended)<br><br>April 16, 2018 (amended)<br><br>September 26, 2018 (amended) | Letter granting EUA amendment(s) (/media/101616/download) (PDF, 155 KB)<br><br>Letter granting EUA amendment(s) (/media/101586/download) (PDF, 123 KB)<br><br>Letter granting EUA amendment(s) (/media/120186/download) (PDF, 110 KB)<br><br>Letter granting EUA amendment(s) (/media/120187/download) (PDF, 113 KB)<br><br>Letter granting EUA amendment(s) (/media/120188/download) (PDF, 131 KB)<br><br>Letter granting EUA amendment(s) (/media/120189/download) (PDF, 131 KB) | FR notice<br>( <a href="https://www.federalregister.gov/articles/2016/03/28/2016-06888/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-diagnosis-of-zika-virus">https://www.federalregister.gov/articles/2016/03/28/2016-06888/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-diagnosis-of-zika-virus</a> ) | <ul style="list-style-type: none"> <li>• Heal (/me KB)</li> <li>• Patie (PDF)</li> <li>• Instr (/me MB)</li> </ul>  |
| CDC Triplex Real-time RT-PCR Assay (Trioplex rRT-PCR)<br><br><i>CDC statement on this EUA</i><br>( <a href="http://www.cdc.gov/media/releases/2016/s0318-zika-lab-test.html">http://www.cdc.gov/media/releases/2016/s0318-zika-lab-test.html</a> )  | March 17, 2016 (initial issuance)<br><br>September 21, 2016 (amended)<br><br>January 12, 2017 (amended)<br><br>February 28, 2017 (amended)<br><br>April 6, 2017 (amended)  | Authorization (/media/96683/download) (PDF, 82 KB)<br><br>Letter granting EUA amendment(s) (/media/100200/download) (PDF, 223 KB)<br><br>Letter granting EUA amendment(s) (/media/102439/download) (PDF, 223 KB)<br><br>Letter granting EUA amendment(s) (/media/103400/download) (PDF, 223 KB)<br><br>Letter granting EUA amendment(s) (/media/120192/download) (PDF, 126 KB)   | FR notice<br>( <a href="https://www.federalregister.gov/articles/2016/04/22/2016-09370/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus">https://www.federalregister.gov/articles/2016/04/22/2016-09370/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus</a> ) | <ul style="list-style-type: none"> <li>• Heal (/me KB)</li> <li>• Patie (PDF)</li> <li>• Instr (/me MB)</li> </ul>  |
| Zika Virus RNA Qualitative Real-Time RT-PCR (Quest Diagnostics Infectious Disease, Inc.)  | April 28, 2016 (initial issuance)<br><br>October 7, 2016 (reissuance)<br><br>April 11, 2017 (amended)  | Authorization (/media/122435/download) (PDF, 339 KB)<br><br>Letter granting EUA amendment(s) (/media/120127/download) (PDF, 126 KB)  | FR notice<br>( <a href="https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus">https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus</a> )   | <ul style="list-style-type: none"> <li>• Heal (/me KB)</li> <li>• Patie (PDF)</li> <li>• Instr (/me KB)</li> </ul>  |
| RealStar Zika Virus RT-PCR Kit U.S. (altona Diagnostics GmbH)   | May 13, 2016 (initial issuance)<br><br>October 31, 2016 (amended)<br><br>March 6, 2017 (amended)   | Authorization (/media/120121/download) (PDF, 342 KB)<br><br>Letter Granting EUA Amendment(s) (/media/120122/download) (PDF, 130 KB)<br><br>Letter Granting EUA Amendment(s) (/media/120123/download) (PDF, 130 KB)   | FR notice<br>( <a href="https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus">https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus</a> )   | <ul style="list-style-type: none"> <li>• Heal (/me KB)</li> <li>• Patie (PDF)</li> <li>• Instr (/me 809)</li> </ul> |

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| Aptima Zika Virus assay (Hologic, Inc.)                                     | June 17, 2016 (initial issuance)<br>September 7, 2016 (amended)<br>April 12, 2017 (amended)<br>March 8, 2018 (amended) | Authorization (/media/120114/download) (PDF, 305 KB)<br>Letter granting EUA amendment(s) (/media/122434/download) (PDF, 126 KB)<br>Letter granting EUA amendment(s) (/media/120116/download)(PDF, 124 KB)<br>Letter granting EUA amendment(s) (/media/120117/download)(PDF, 130 KB) | FR notice (https://www.federalregister.gov/articles/2016/07/08/2016-16177/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-zika-virus)                | <ul style="list-style-type: none"> <li>• Heal (/me (PDF</li> <li>• Patie (PDF</li> <li>• Instr (/me (PDF</li> </ul> |
| Zika Virus Real-time RT-PCR Test (Viracor Eurofins)                         | July 19, 2016 (initial issuance)<br>February 28, 2017 (amended)  | Authorization (/media/120033/download) (PDF, 334 KB)<br>Letter granting EUA amendment(s) (/media/120034/download) (PDF, 124 KB)   | FR notice (https://www.federalregister.gov/articles/2016/09/07/2016-21353/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus#h-6)       | <ul style="list-style-type: none"> <li>• Heal (/me (PDF</li> <li>• Patie (PDF</li> <li>• Instr (/me (PDF</li> </ul> |
| VERSANT Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics Inc.) | July 29, 2016 (initial issuance)<br>December 19, 2016 (amended)  | Authorization (/media/99444/download) (PDF, 78 KB)<br>Letter granting EUA amendment(s) (/media/120030/download) (PDF, 124 KB)   | FR notice (https://www.federalregister.gov/documents/2016/10/28/2016-26066/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-andor-diagnosis-of-zika-virus) | <ul style="list-style-type: none"> <li>• Heal (/me KB)</li> <li>• Patie (PDF</li> <li>• Instr (/me KB)</li> </ul>   |
| Sentosa SA ZIKV RT-PCR Test (Vela Diagnostics USA, Inc.)                    | September 23, 2016   | Authorization (/media/120017/download) (PDF, 355 KB)  | FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)           | <ul style="list-style-type: none"> <li>• Heal (/me (PDF</li> <li>• Patie (PDF</li> <li>• Instr (/me MB)</li> </ul>  |
| Zika Virus Detection by RT-PCR Test (ARUP Laboratories)                     | September 28, 2016   | Authorization (/media/120014/download) (PDF, 98 KB)   | FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)           | <ul style="list-style-type: none"> <li>• Heal (/me KB)</li> <li>• Patie (PDF</li> <li>• Instr (/me (PDF</li> </ul>  |
| Abbott RealTime ZIKA (Abbott Molecular Inc.)                                | November 21, 2016 (initial issuance)<br>January 6, 2017 (amended)  | Authorization (/media/101657/download) (PDF, 84 KB)<br>Letter granting EUA amendment(s) (/media/120010/download) (PDF, 150 KB)  | FR notice (https://www.federalregister.gov/documents/2016/12/20/2016-30532/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)          | <ul style="list-style-type: none"> <li>• Heal (/me 208</li> <li>• Patie (PDF</li> <li>• Instr (/me MB)</li> </ul>   |

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| Zika ELITe MGB Kit U.S. (ELITechGroup Inc. Molecular Diagnostics) | December 9, 2016 | Authorization (/media/119919/download) (PDF, 312 KB) | FR notice (https://www.federalregister.gov/documents/2017/01/09/2017-00084/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus) | <ul style="list-style-type: none"> <li>• Heal (/me 213)</li> <li>• Patie (PDF)</li> <li>• Instr (/me (PDF)</li> </ul> |
| Gene-RADAR Zika Virus Test (Nanobiosym Diagnostics, Inc.)         | March 20, 2017   | Authorization (/media/119915/download) (PDF, 313 KB) | FR notice (https://www.federalregister.gov/documents/2017/06/30/2017-13720/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-of-zika-virus)        | <ul style="list-style-type: none"> <li>• Heal (/me 267)</li> <li>• Patie (PDF)</li> <li>• Instr (/me (PDF)</li> </ul> |
| TaqPath Zika Virus Kit (Thermo Fisher Scientific)                 | August 2, 2017   | Authorization (/media/119906/download) (PDF, 292 KB) | FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)  | <ul style="list-style-type: none"> <li>• Heal (/me 252)</li> <li>• Patie (PDF)</li> <li>• Instr (/me (PDF)</li> </ul> |
| CLL-ArboViroPlex rRT-PCR Assay (Columbia University)              | August 11, 2017  | Authorization (/media/107073/download) (PDF, 377 KB) | FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)  | <ul style="list-style-type: none"> <li>• Heal (/me 229)</li> <li>• Patie (PDF)</li> <li>• Instr (/me (PDF)</li> </ul> |

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- [Summary of Process for EUA Issuance \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance\)](#)
- [Current Emergency Use Authorizations for Medical Devices \(/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices\)](#)
- [How to Submit a Pre-EUA for \*In vitro\* Diagnostics \(IVDs\) to FDA \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-vitro-diagnostics-fda\) \(for test manufacturers\)](#)
- [Information for Laboratories Implementing IVD Tests Under EUA \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua\)](#)
- [Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019 \(https://www.federalregister.gov/documents/2020/06/02/2020-11898/process-for-publishing-emergency-use-authorizations-for-medical-devices-during-coronavirus-disease\) \(June 2, 2020\)](#)
- [Emergency Use Authorization--Archived Information \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information\)](#)
- [Emergency Dispensing Orders \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders\)](#)

- 21st Century Cures Act: MCM-Related Cures Provisions (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions)
- Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pandemic-and-all-hazards-preparedness-reauthorization-act-2013-pahpra)
- Public Readiness and Emergency Preparedness (PREP) Act (<https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx>)
- HHS Public Health Emergency EUA Authorization Declarations (<http://www.phe.gov/emergency/news/healthactions/Lists/EUA/AllItems.aspx>)
- Ebola Preparedness and Response Updates from FDA (/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda)
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